

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION**

**PLANNED PARENTHOOD MINNESOTA,  
NORTH DAKOTA, SOUTH DAKOTA, and  
SARAH A. TRAXLER, M.D.;**

**Plaintiffs,**

**v.**

**KRISTI NOEM, Governor,  
JOAN ADAM, Interim Secretary of  
Health, Department of Health, and  
PHILIP MEYER, D.O., President, South  
Dakota Board of Medical and  
Osteopathic Examiners, in their official  
capacities,**

**Defendants.**

**CASE NO. 22-4009**

**PLAINTIFFS' BRIEF IN SUPPORT OF THEIR MOTION FOR A  
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Diana O. Salgado\*  
Planned Parenthood Federation of America  
1110 Vermont Avenue, NW, Suite 300  
Washington, District of Columbia 20005  
Telephone: (212) 261-4399  
diana.salgado@ppfa.org

Michael Drysdale\*  
Dorsey & Whitney LLP  
50 South Sixth St., Suite 1500  
Minneapolis, MN 55402  
Telephone: (612) 340-5652  
drysdale.michael@dorsey.com

Stephanie Amiotte (SD Bar #3116)  
Andrew Malone (SD Bar #5186)  
American Civil Liberties Union of North  
Dakota, South Dakota, and Wyoming  
PO Box 91952  
Sioux Falls, SD 57109  
Telephone: (605) 332-2508  
samiotte@aclu.org  
amalone@aclu.org

ATTORNEYS FOR PLAINTIFFS

\*Application for admission *pro hac vice*  
forthcoming

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## INTRODUCTION

Plaintiffs seek a temporary restraining order and preliminary injunction to block enforcement of portions of South Dakota Department of Health Rule 44:67:04:13 (the “Rule”), which would irreparably harm South Dakotans seeking to exercise their constitutional liberty and privacy rights to choose to have an abortion. Absent an injunction from this Court, the Rule is scheduled to take effect January 27, 2022—the same day on which abortion services are next scheduled to occur at the only health center in South Dakota that provides abortions.

The State of South Dakota has been unrelenting in its effort to infringe the rights of South Dakotans to access safe abortion services. Currently, state law requires that patients make two trips to a clinic in order to obtain an abortion. Existing state law also imposes a minimum 72-hour delay (excluding weekends and holidays), between the first and second visits, and precludes the delivery of medication abortion (a safe, early method of abortion using pills alone) via telemedicine without an in-person physician interaction despite that medication abortion can be—and in many states is—provided safely and effectively both by non-physicians and via telemedicine. Existing legal restrictions also limit abortion services to the first trimester, and due to the hyper-regulation of abortion and enormous political stigma associated with abortion in South Dakota, Planned Parenthood Minnesota, North Dakota, South Dakota (“PPMNS”) is limited to providing abortion services 2-3 times per month. And although presently enjoined, the State is also seeking to force abortion patients to visit an anti-abortion center within the 72-hour delay. The challenged Rule would pile on one more restriction—and another health center visit—that provides no medical benefit to patients.

The challenged Rule, issued in response to an executive order from the Governor but going beyond its stated objectives, targets medication abortion, a non-invasive and non-surgical method

of abortion. Medication abortion involves taking two medications, 24 to 48 hours apart. Rather than allowing the second medication to be dispensed at the patient's second visit, which has been the standard of care in South Dakota and around the country for more than twenty years, the Rule would impose an additional in-person visit requirement 24 to 72 hours after the second visit, solely for the purpose of dispensing the second medication, misoprostol. This defies the recommendations of the Food and Drug Administration ("FDA") and leading state and national medical organizations. The Rule will impose severe obstacles to abortion access for South Dakotans and may subject patients to unnecessary health risks, with absolutely no benefit to health and safety, in violation of their constitutional rights.

## FACTS

### I. Medication Abortion in South Dakota

There are two methods of abortion in the first trimester: medication and procedural (also sometimes referred to as "surgical") abortion. Decl. of Sarah A. Traxler, M.D. ("Traxler Decl.") ¶11; Decl. of Daniel A. Grossman, M.D. ("Grossman Decl.") ¶25. Plaintiff PPMNS is the only generally available abortion provider in South Dakota and provides medication abortions through 77 days of pregnancy as measured from the first day of the patient's last menstrual period ("LMP"), and it provides procedural abortions through 13.6 weeks LMP. Traxler Decl. ¶11.

Medication abortion involves a regimen of two FDA-approved prescription drugs: mifepristone and misoprostol, which cause the patient to expel the pregnancy in a manner clinically similar to a miscarriage. *Id.* ¶13; Grossman Decl. ¶11. Mifepristone, which is taken first, blocks the body's receptors to progesterone, a hormone necessary to sustain pregnancy. Misoprostol, which causes the uterus to contract and empty, is taken 24 to 48 hours later. Most patients abort within 24 hours of taking misoprostol, and some as soon as within two hours. Traxler Decl. ¶17;

Grossman Decl. ¶17. Medication abortion is extremely safe, comparable to medications like ibuprofen and antibiotics. Traxler Decl. ¶15; Grossman Decl. ¶12. While misoprostol can safely be taken on its own, taking mifepristone without later taking misoprostol has been shown to put patients at increased risk of significant complications, including hemorrhage. Traxler Decl. ¶¶37–38; Grossman Decl. ¶47.

Medication abortion accounts for about 40% of abortions nationwide and in South Dakota. Traxler Decl. ¶¶11–12; Grossman Decl. ¶27. There are a variety of reasons why a person might prefer a medication abortion to a procedural one. For example, a medication abortion may feel more private and allow patients more flexibility; it is also less invasive. Traxler Decl. ¶64; Grossman Decl. ¶28. Some patients choose medication abortion because it resembles miscarriage, making it easier to conceal from an abusive partner or family member. Traxler Decl. ¶64; Grossman Decl. ¶28. Moreover, there is a subset of patients for whom medication abortion is considered safer than procedural abortion. Traxler Decl. ¶65; Grossman Decl. ¶30. Medication abortion is also an important tool for enabling people to access care earlier in their pregnancy.

Due to existing state abortion restrictions, abortion patients must have two, in-person visits with the same physician at the health center, three days apart, excluding weekends and holidays. S.D.C.L. §34-23A-56. First, patients must meet with a physician to begin the state-mandated informed consent process. Then, no sooner than 72 hours later, they must return to the clinic to finalize informed consent, complete forms, and obtain their abortion. For medication abortions, the physician dispenses both mifepristone, which is taken at the health center, and misoprostol, which is self-administered 24 to 48 hours later, at a location of their choosing. Traxler Decl. ¶¶30–31. This statutory regime disallows the use of telemedicine for abortion. Instead, some patients must travel great distances—twice—to reach Sioux Falls. *Id.* ¶40.

Many of the health center’s patients have low incomes. *Id.* ¶¶39, 44. Many are already mothers, have jobs, or go to school. *Id.* ¶39. All of these responsibilities must be put on hold each time the patient travels to Sioux Falls. For some of these patients, especially those who are victims of sexual assault or domestic violence or who are trying to keep their abortion from an abusive partner or family member, each trip poses an additional risk. *Id.* ¶47; Grossman Decl. ¶33. And due to abortion stigma and extremely limited physician availability, abortions are currently only offered two times a month in South Dakota. Traxler Decl. ¶¶51–53, 57. All of these factors already make it exceedingly difficult for patients to obtain abortion care. *Id.* ¶57.

## II. FDA Regulation of Medication Abortion and the REMS Change

Despite decades of research demonstrating the safety and efficacy of medication abortion, the FDA has subjected mifepristone to a federal Risk Evaluation and Mitigation Strategy (“REMS”) which, until recently, required “in-person dispensing” of *mifepristone*—meaning that it could not be dispensed at commercial pharmacies. Grossman Decl. ¶18. In contrast, misoprostol has *never* been subject to a REMS and has been readily available at commercial pharmacies with a prescription since it was first approved for gastric ulcer treatment decades ago. *Id.* ¶19. Misoprostol is extremely safe, and routinely prescribed in various treatment regimens beyond medication abortion, including for the treatment of incomplete abortions, miscarriage management, postpartum hemorrhage, difficult IUD insertion/removal, and gastric ulcers. *Id.* ¶¶13, 15, 21, 31; Traxler Decl. ¶¶23–25. Its use in medication abortion is particularly safe, with a lower risk of bleeding than when used for management of incomplete abortion, postpartum hemorrhage, and miscarriage. Grossman Decl. ¶31.

Prompted in part by the COVID-19 pandemic, the FDA temporarily suspended the in-person dispensing requirement for mifepristone in April 2021 and made this change permanent in

December 2021. *Id.* ¶18. Because mifepristone could now be dispensed without an in-person visit, the practical effect of the REMS change was to increase access to medication abortion, because providers can now meet with a patient via telemedicine and then mail the medications to the patients themselves or through a mail-order pharmacy (to the extent allowed by state law). However, because of existing state laws, *supra*, South Dakota was unaffected by this change. Notably, neither the pandemic, nor the temporary relaxation of the REMS, nor the recent permanent relaxation of the REMS, had any effect on the dispensation of misoprostol, because misoprostol was not subject to the REMS.

### **III. Governor Noem’s Executive Order and the Rule**

On November 7, 2021, prompted by the anticipated FDA REMS change, Governor Noem issued Executive Order 2021-12 (“EO 2021-12”), Compl., Ex. B, which directed the South Dakota Department of Health (“Department”) to issue rules to ensure that telemedicine was not permitted for abortion—despite already being precluded under existing laws. The Department’s response to EO 2021-12 was similarly irrational. Rather than promulgate a Rule related to mifepristone (the subject of the REMS change), the Department issued a rule requiring medication abortion patients to make a third, in-person visit with a physician solely for the purpose of picking up *misoprostol*.

The Department filed the final version of the Rule on January 7, 2022, and it is scheduled to take effect on January 27, 2022. The Rule states in relevant part: “[b]etween 24–72 hours after taking Mifepristone, if the pregnant woman decides to continue with the medical abortion, the pregnant woman must return to the licensed abortion facility to receive the proper amount of Misoprostol. . . . Neither Mifepristone nor Misoprostol may be dispensed for the purpose of inducing a medical abortion in any manner contrary to this section.” Rule 44:67:04:13, Compl., Ex. A. Violating the Rule is grounds for revoking Plaintiffs’ licenses. S.D. Admin. R.

44:67:01:05(1); S.D.C.L. §36-4-29. The Rule does not apply to misoprostol prescribed *in any other setting*, and the State does not impose similar restrictions on any other drug.

#### **IV. Impact of the Rule on Abortion Access**

The Rule will have immediate and devastating effects on abortion access. First, the Rule would unnecessarily harm patients. Traxler Decl. ¶¶36–48; Grossman Decl. ¶¶41–67. It would require PPMNS to provide care that is contrary to best medical practices and contrary to the guidance of both the American College of Obstetricians and Gynecologists (“ACOG”) and the FDA. Traxler Decl. ¶¶22, 24, 33; Grossman Decl. ¶¶15–16, 21, 55. It also imposes severe burdens. For reference, the Rule’s third-trip requirement would mean that almost a quarter of patients would need to travel 450 miles total to get a medication abortion and more than a tenth would travel over 900 miles. Traxler Decl. ¶41. Requiring a third trip to the clinic solely for the dispensation of misoprostol would require time and resources that many of PPMNS’s patients simply do not have, thereby delaying or denying them access to a safe, early method of abortion. In 2021, about 22% of the clinic’s medication abortion patients had an abortion at 10 weeks LMP, *id.* ¶73, which means for a significant percentage of patients, any further delays could push them beyond the gestational age limit for a medication abortion.

Even if patients think they may be able to surmount these obstacles to return for a third visit, travel plans can easily be upended by unforeseen circumstances, such as weather or illness. Traxler Decl. ¶¶42–43; Grossman Decl. ¶45. For patients whose care is interrupted mid-regimen, this Rule may unnecessarily increase their chance of hemorrhage, or cause them further delay in accessing care. Traxler Decl. ¶¶37–38, 74; Grossman Decl. ¶¶44, 47–48. PPMNS will not subject patients to these increased health risks and other harms, with absolutely no medical benefits. Traxler Decl. ¶¶49, 76. But even if PPMNS did not have ethical and safety concerns about the



Rule, it still could not comply. The clinic's providers are not able to accommodate a third visit to Sioux Falls within the strict time frames mandated by existing state law, the Rule, and the medication regimen itself. *Id.* ¶58. The handful of South Dakota-licensed physicians who provide abortions currently travel long distances to Sioux Falls twice in one week to comply with already onerous abortion requirements. *Id.* ¶56. Because of other professional responsibilities, these physicians are unable to return to Sioux Falls a third time simply to hand patients pills 24 to 48 hours later—the window of time that is recommended for patients to take the misoprostol. *Id.* ¶58. Nor can they stay overnight, assuming patients could even return 24 hours later. *Id.*

As a result, Plaintiffs will be forced to stop providing medication abortions in South Dakota, meaning that none of the patients who prefer or require medication abortion will be able to receive their treatment of choice, and some may not be able to receive an abortion at all. *Id.* ¶¶64–65; Grossman Decl. ¶¶27–30. The impact of the Rule will be felt by *all* South Dakota abortion patients because procedural abortion takes more time. If Plaintiffs can offer only procedural abortion, the number of available appointments for patients would be reduced by about 30%. Traxler Decl. ¶67. This would result in patients being delayed in receiving care, or sometimes timing-out of care altogether. Traxler Decl. ¶¶67, 72–75; Grossman Decl. ¶¶37, 44, 56. Even though abortion is an extremely safe procedure, its risks increase with gestational age. Traxler Decl. ¶68; Grossman Decl. ¶36. And for many patients waiting for an abortion is not medically advisable. Traxler Decl. ¶68; Grossman Decl. ¶52. Those who are forced to carry unwanted pregnancies to term could face ensuing risks to their physical, mental, and emotional health, as well as to that of their family. Traxler Decl. ¶69; Grossman Decl. ¶¶63–65.

The burdens of delaying and forgoing care would be experienced only by abortion patients, as the Rule creates an arbitrary classification between different types of misoprostol use and

prescription. Prescription of misoprostol in connection with management of incomplete abortion, management of postpartum hemorrhage, and miscarriage management actually involves a higher risk of bleeding than does its prescription for medication abortion. Grossman Decl. ¶31. Yet the Rule does not regulate misoprostol dispensation in any of these circumstances.

## **ARGUMENT**

Plaintiffs’ motion is governed by a four-part test, in which this Court considers (1) Plaintiffs’ likelihood of success on the merits, (2) the threat of irreparable harm, (3) the balance of equities, and (4) the public interest. *See Grasso Enters., L.L.C. v. Express Scripts, Inc.*, 809 F.3d 1033, 1036 n.2 (8th Cir. 2016) (citing *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc)). Although Plaintiffs also meet the more stringent “likely to prevail” standard, because Plaintiffs seek to block an agency rule adopted pursuant to the Governor’s executive-order directive which lacks the benefit of “presumptively reasoned democratic processes,” the “likelihood of success” inquiry asks only whether Plaintiffs have a “fair chance of prevailing.” *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng’rs*, 826 F.3d 1030, 1040 (8th Cir. 2016) (quoting *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732 & n.6 (8th Cir. 2008) (en banc)). In the Eighth Circuit, the same standard applies to requests for temporary restraining orders and preliminary injunctions. *See S.B. McLaughlin & Co. v. Tudor Oaks Condo. Project*, 877 F.2d 707, 708 (8th Cir. 1989). For the reasons below, Plaintiffs readily satisfy this four-factor inquiry.

### **I. Plaintiffs Have Established Likelihood of Success on the Merits of Their Claims.**

#### **A. The Mandatory Delay and Third-Visit Requirement For Misoprostol Will Unduly Burden Patients.**

It is well-established that a State cannot “impose an undue burden on the woman's ability to obtain an abortion.” *Hopkins v. Jegley*, 968 F.3d 912, 914 (8th Cir. 2020) (per curiam) (quoting

*Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877 (1992)). To determine if an undue burden exists, the Eighth Circuit treats Chief Justice Roberts’s concurring opinion in *June Medical Services L.L.C. v. Russo*, 140 S.Ct. 2103, 2135 (2020) as controlling. *Jegley*, 968 F.3d at 914–15. Under C.J. Roberts’s concurrence, a law imposes an undue burden if it is not “reasonably related” to a “legitimate purpose,” or has the “effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.” *Id.* at 915 (quoting *June Med.*, 140 S.Ct. at 2138). Here, the Rule fails both prongs of this test.

### **1. The Rule is Not Reasonably Related to a Legitimate Purpose.**

C.J. Roberts’s concurrence made clear that *Casey* imposes a “threshold requirement” that laws regulating abortion must have a “legitimate purpose” and be “reasonably related to that goal.” *June Med.*, 140 S.Ct. at 2138. Thus, as is the case here, where the “State requires licensing [and] undertakes to regulate the performance of abortions . . . the health standards adopted must be legitimately related to the objective the State seeks to accomplish.” *City of Akron v. Akron Ctr. for Reprod. Health*, 462 U.S. 416, 431 (1983) (cleaned up), *rev’d on other grounds*, *Casey*, 505 U.S. 833. Defendants cannot meet that threshold showing because not only does the Rule go beyond the State’s asserted goals and fails to meet them, but the Rule is also far outside of the standard of care and, in fact, may put patients at increased health risks.

The Department has asserted that the Rule is “required per the Governor’s Executive Order 2021-12,”<sup>1</sup> which ordered the Department to promulgate rules to negate the FDA REMS change. Specifically, EO 2021-12 stated its purpose was to prevent the use of telemedicine for abortion and “the dispensing of mifepristone through the mail or through a mail-order pharmacy.”<sup>2</sup> The

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<sup>1</sup> S.D. Dep’t of Health, *Form 14, Small Business Impact Statement Form*, [https://rules.sd.gov/Uploads/684\\_BusinessImpactStatement.pdf](https://rules.sd.gov/Uploads/684_BusinessImpactStatement.pdf).

<sup>2</sup> Exec. Order No. 2021-12 (S.D. 2021). *See also* S.D. State News, *Pro-Life Rule Blocking Telemedicine Abortions Approved* (Jan. 6, 2022), <https://news.sd.gov/newsitem.aspx?id=28824>

Department has also stated that the Rule is necessary “to protect the health and safety of women that is [*sic*] at-risk due to the expected FDA lifting of additional safety protocols regarding the use of mifepristone and misoprostol,”<sup>3</sup> and that “the purpose of the rule” is to “requir[e] in-person dispensing of both of these drugs,” and that “[t]he drugs must be prescribed, dispensed in a licensed abortion facility.”<sup>4</sup>

The Department is flat out wrong that the FDA was going to or did take any action with respect to misoprostol. That is because the FDA’s REMS has always addressed only mifepristone. Grossman Decl. ¶19. As EO 2021-12 explains, the FDA “review[ed] the elements of the . . . (REMS) for mifeprex and its approved generic, mifepristone tablets,”<sup>5</sup> and then announced its decision to eliminate the in-person dispensing requirement for *mifepristone*. Indeed, EO 2021-12 does not once refer to federal in-person dispensation restrictions on misoprostol.<sup>6</sup> That is because these have never existed. Grossman Decl. ¶¶14–16, 19. Because misoprostol is frequently prescribed for other indications, it is regularly prescribed to patients and dispensed at pharmacies with instructions on how to take it at home. *Id.* at ¶¶19–23.

Thus, even assuming without conceding that codifying the REMS’s previous requirement that mifepristone be dispensed in a health center could be a legitimate interest, the Rule’s restrictions on the dispensing of misoprostol are not reasonably related to this interest. Patients are already dispensed misoprostol in the health center at a physician visit. But the Rule takes that

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(Gov. Noem stating: “I look forward to the day when the life of every unborn child is protected in South Dakota. Until then, South Dakotans will know that if a mother uses abortion pills to end her unborn child’s life, she will not get those pills from a stranger over the internet.”)

<sup>3</sup> S.D. Dep’t of Health, *Form 6, Notice of Public Hearing to Adopt Rules § 44:67:04:13*, [https://rules.sd.gov/Uploads/684\\_PublicNotice.pdf](https://rules.sd.gov/Uploads/684_PublicNotice.pdf).

<sup>4</sup> *Four Hundred Fourth Meeting, Interim Rules Rev. Comm.*, (S.D. Dec. 27, 2021) (statement of Ally Turnow, Staff Att’y, S.D. Dep’t of Health).

<sup>5</sup> Exec. Order, *supra* note 2.

<sup>6</sup> *See id.*

further and forces them to wait a minimum of 24 hours before it can be dispensed to them at another physician visit. That waiting period and additional visit requirement—something that the FDA has never required—is in no way reasonable, or tethered to the Executive Order.

Nor can the Rule be justified by a purported need to ensure telemedicine abortion does not proliferate. While the Department claims that its interests are to require “[t]he drugs . . . be prescribed, dispensed in a licensed abortion facility,”<sup>7</sup> these interests are already met by existing laws. Patients already dispense both mifepristone and misoprostol on the same day, by a licensed physician, during the second in-person visit at a licensed abortion facility. Traxler Decl. ¶31. As a result, South Dakota patients are precluded from using telemedicine to have a medication abortion, regardless of whether the federal REMS or the Rule are in place or not.

In fact, the REMS’s in-person dispensing requirement has been suspended since April 2021, and there is zero evidence of resulting negative health outcomes anywhere in the country, including in the states that allow the medications to be mailed to patients after a telemedicine visit. Nor is there evidence that medication abortion has *ever* been provided in South Dakota “via courier delivery, telemedicine or mail service.” Simply put, there is nothing reasonable about the Rule, much less about its relationship to an Executive Order—about a different medication—that was issued in response to a REMS change that had no effect in South Dakota.

Indeed, throughout the rulemaking process—including three public hearings—the Department has failed to present any evidence that could support a legitimate basis for the Rule. This is true for the Rule as a whole, but especially true of the Rule’s mandatory delay and separate visit requirements for the dispensing of misoprostol. At every step of the process, Plaintiffs made clear to the Department that South Dakota law already disallows abortion by telemedicine and that

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<sup>7</sup> *Four Hundred Fourth Meeting*, *supra* note 4.

both mifepristone and misoprostol are already dispensed by a physician at a health center. Traxler Decl., Ex. B. The Department failed to provide any evidence to establish that the manner in which misoprostol is currently dispensed (on the same day of the mifepristone) raises any safety and health concerns. Nor could it. In fact, it is the Rule that threatens patients' health because it increases the likelihood that patients will interrupt the medication-abortion regimen if they cannot make the extra trip. There is evidence that taking the mifepristone, but not taking the misoprostol, may actually increase the risk of hemorrhage for patients. Traxler Decl. ¶¶37–38; Grossman Decl. ¶¶47–48.

At bottom, the Rule is a drastic departure from the standard of care that has been in place for over twenty years, supported by robust research demonstrating that women can be dispensed both medications at the same time and can safely self-administer the misoprostol at home. Indeed, the FDA considered this very issue and concluded that: “There is no medical rationale against permitting the woman to be given the misoprostol on the day of the initial clinic/office visit and self-administer it at a convenient time in the next 24–48 hours at home.” Grossman Decl. ¶15. But the Department ignored the FDA. It ignored the guidance of ACOG, the nation's leading relevant physician group. It ignored the South Dakota State Medical Association, which told it that the Rule's restrictions on misoprostol were “clinically unnecessary” and do “nothing more than create another barrier for the patient that may result in an increased risk of hemorrhage and bad outcome.” S.D. State Med. Ass'n Comments, Compl., Ex. C. And it ignored the State's existing laws and experience, which shows no adverse effects under the existing drug regimen.

For these reasons, Plaintiffs have a fair chance of prevailing (and moreover are likely to succeed) on their claim that the Rule is not reasonably related to a legitimate government interest. *See Akron Ctr. for Reprod. Health*, 462 U.S. at 430–31 (quoting *Roe v. Wade*, 410 U.S. 113, 163

(1973)) (State must meet its burden of showing that regulation “reasonably relates to the preservation and protection of maternal health”); *see also id.* at 431 (“The State’s discretion to regulate on this basis [of protecting maternal health] does not, however, permit it to adopt abortion regulations that depart from accepted medical practice.”); *id.* at 438 (striking an “unnecessary” regulation on clinics); *see also Casey*, 505 U.S. at 900–01 (recognizing recordkeeping and reporting requirements as “a vital element of medical research” that were ““reasonably directed to the preservation of maternal health”” (quoting *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 80 (1976))).

## **2. The Rule Would Impose a Substantial Obstacle on Patients Seeking Abortions.**

Separately, the Rule also has the effect of placing a substantial obstacle in the path of a woman’s choice. Here, the Rule has the practical result of banning medication abortion entirely, depriving patients of a safe non-procedural option they have had for years, which is strongly preferred by many and medically indicated for some. By forcing all South Dakota patients to have a procedural abortion, the Rule will cause delays to access to treatment due to the limited availability of abortion services. This would increase risks to patients’ health and for some, bar them from obtaining an abortion in South Dakota, or potentially at all. Even if Plaintiffs could comply with the Rule, it still imposes an undue burden for those who cannot travel three times to the health center in the windows prescribed by the State. It would also result in overall reduced capacity, causing delays in all patients’ ability to access the time-sensitive care they need.

### **a. The Rule Would Eliminate Access to Medication Abortion.**

The effect of the Rule would be to eliminate access to medication abortion in South Dakota. As described above, the Rule is contrary to the standard of care and imposes severe burdens on patients, including possibly increasing health risks, with no countervailing medical benefit. Under

these circumstances, PPMNS would have to cease providing medication abortions rather than provide care in this manner. Even if PPMNS did not have ethical and safety concerns about the Rule, PPMNS simply would not be able to staff the Sioux Falls clinic to comply with the Rule. For these reasons, the Rule would prevent PPMNS from providing medication abortion, leaving patients without access to the abortion method of their choice.

When considering the burdens imposed by the Rule, one group for whom the law is relevant is, plainly, patients who choose to have a medication abortion. *See Planned Parenthood Minn., N.D., S.D. v. Daugaard*, 799 F.Supp.2d 1048, 1064 (D.S.D. 2011) (in assessing undue burden, the court considers whether the restriction “create[s] a ‘substantial obstacle to the woman’s choice to undergo an abortion’ in those cases where the [Rule] is ‘relevant’”, meaning those “for whom the law is a restriction, not the group for whom the law is irrelevant.” (internal citations omitted)). If the Rule takes effect, 100% percent of these patients would be unduly burdened, as they would be prevented from having a non-invasive and non-surgical method of abortion in South Dakota. *See e.g., Planned Parenthood Ark. & E. Okla. v. Jegley for Pulaski Cnty.*, No. 4:15-CV-00784-KGB, 2018 WL 3029104, at \*16 (E.D. Ark. June 18, 2018) (noting that “100% of ‘women seeking medication abortions in Arkansas,’ are burdened” by the law at issue (quoting *Planned Parenthood of Ark. & E. Okla. v. Jegley*, 864 F.3d 953, 959 (8th Cir. 2017)); *see also June Med.*, 140 S.Ct. at 2130 (plurality opinion) (considering in burden analysis that challenged law would increase medical risk from delayed care, including losing the option for a “noninvasive medication abortion”).

Patients who choose medication abortion—approximately 40% of patients—do so for a variety of personal and deeply held reasons. Some see medication abortion as more private or affording them more flexibility to meet their other obligations. Because the process closely



resembles a miscarriage, it is also often preferred by patients who are trying to conceal their abortion from an abusive or coercive partner or family member. Others prefer medication abortion because it does not involve the insertion of instruments into their vagina; this is particularly important for patients who have suffered sexual violence. For yet another subset of patients, medication abortion is medically indicated. A complete ban on medication abortion would substantially burden all of these patients.<sup>8</sup> Traxler Decl. ¶¶64–65; Grossman Decl. ¶¶27–30.

As courts have recognized, laws that ban a safe, effective, commonly-used abortion method impose an impermissible burden. *See Stenberg v. Carhart*, 530 U.S. 914, 915–16, 924 (2000) (striking down ban on “the most commonly used” second trimester procedure); *Danforth*, 428 U.S. at 78 (same); *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 917 (9th Cir. 2014) (enjoining law which, in part, “prohibit[ed] medication abortion entirely, leaving surgical abortion as the only legal alternative” for patients “between 49 and 63 days LMP”); *Cf. Gonzales v. Carhart*, 550 U.S. 124, 135, 156 (2007) (federal ban on “partial-birth abortion” upheld because it would not “prohibit the vast majority of” “the usual abortion method” in the second trimester); *Am. Coll. of Obstetricians & Gynecologists v. United States FDA*, 472 F.Supp.3d 183, 210 (D. Md. 2020) (“[A] restriction can impose an undue burden even if it does not entirely prevent women from obtaining an abortion of any kind.”), *appeal dismissed*, No. 20-1784, 2021 WL 3276054 (4th Cir. May 19, 2021). *But see, e.g., Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 516 (6th Cir. 2012) (“The Court has not extended constitutional protection to a woman” preferred method . . .

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<sup>8</sup> “The fact that some of the women who prefer medication abortions will nonetheless receive a surgical abortion does not affect this analysis.” *Jegley for Pulaski Cnty.*, 2018 WL 3029104, at \*16. Moreover, “removing medication abortion as an option for women will result in negative consequences for those . . . for whom medication abortion is medically indicated.” *Id.*

.’); *Whole Woman’s Health v. Paxton*, 10 F.4th 430, 453 (5th Cir. 2021) (finding that Texas law did not ban second-trimester abortions “[b]ecause there are safe, medically recognized alternatives”).

**b. The Rule Would Lead to an Overall Reduction in Abortion Services.**

Furthermore, if the Rule prevents Plaintiffs from providing medication abortion, the effect will be a 30% reduction in available appointments for patients, creating further barriers to patients’ ability to access abortion. Because procedural abortions are more time-intensive than medication abortions, PPMNS would have to perform fewer abortions in total if it could only offer that method. Traxler Decl. ¶¶66–67. Patients are currently scheduled about 4 weeks out just to meet existing demand. *Id.* at ¶67. Under the Rule, patients would have to be scheduled even further out given that there would be substantially fewer appointments available. Given that Plaintiffs are the only generally available abortion provider in the state, and per legal restrictions can only provide abortions through 13.6 weeks LMP, a 30% reduction in appointments would cause significant delays for patients and would likely increase the number of people who could not obtain an abortion in South Dakota. “It stands to reason that the number of women who are effectively denied their right to undergo an abortion increases as the required period of delay increases.” *Daugaard*, 799 F.Supp.2d at 1065; *cf. Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 796 (7th Cir. 2013) (noting “[p]atients will be subjected to weeks of delay because of the sudden shortage of eligible doctors”), *cert. denied*, 573 U.S. 931 (2014).

Increased delays will expose patients to increased health risks. Even though abortion is an extremely safe procedure, its risks increase with gestational age. Grossman Decl. ¶36; *see also Humble*, 753 F.3d at 915-17 (“[D]elay in abortion increases health risks.” (quoting *Tucson Woman’s Clinic v. Eden*, 379 F.3d 531, 542 (9th Cir. 2004))); *Planned Parenthood of Wis., Inc. v.*

*Schimel*, 806 F.3d 908, 920 (7th Cir. 2015) (explaining delay “compel[s] some women to defer abortion to the second trimester of their pregnancy—which the studies . . . find to be riskier than a first-trimester abortion”). There are also many patients for whom waiting for their abortion would not be medically advisable. Traxler Decl. ¶¶68; *Planned Parenthood Se., Inc. v. Strange*, 33 F.Supp.3d 1330, 1355 (M.D. Ala. 2014) (explaining that under law, people would be “delayed in obtaining abortions, exposing them to greater risks of complications”).

For those patients who cannot get an appointment before 13.6 weeks LMP due to the additional delays caused by the Rule—the group for whom the Rule will operate as a ban—their only option to access abortion would be to attempt travel out of state. Reduced access to abortion in the form of increased travel distance independently delays patients, and in some cases prevents people from accessing care altogether. Grossman Decl. ¶¶58–59. These patients will be forced to either carry to term against their will, or attempt to terminate their pregnancies outside the health care system.

For all of these additional reasons, the Rule constitutes an undue burden, as it will lead to “longer waiting times,” “increased crowding,” “delays,” “increased driving distances,” and “increase[d] . . . risk that a woman will experience complications from the procedure.” *June Med.*, 140 S.Ct. at 2129–30 (plurality opinion); *see also id.* at 2140 (Roberts, C.J., concurring) (recognizing burdens from “increased associated health risk”); *Whole Woman’s Health*, 136 S.Ct. 2292, 2316–18 (2016) (inability of remaining clinics to accommodate demand after other clinics shut down showed that requirement was an undue burden); *Jegley*, 864 F.3d at 958 (recognizing clinic-capacity issues could burden women); *Humble*, 753 F.3d at 915 (discussing in undue burden analysis “the frequency with which clinics can see patients”).

**c. Even If Plaintiffs Could Comply with the Rule, It Would Still Impose a Substantial Obstacle.**

Even if Plaintiffs could comply with the Rule, there is still no doubt that it would operate as a substantial obstacle for patients because it would impose significant travel and logistical burdens. Travel burdens are already exacerbated by South Dakota's existing 72-hour mandatory delay and two-trip requirement.<sup>9</sup> The Rule would force patients seeking a medication abortion to make a *third, additional* trip within a narrow 24 to 48 hour window, substantially compounding existing burdens.

In an ongoing case challenging a South Dakota law that would force abortion patients to visit an anti-abortion center during the 72-hour waiting period law, this Court described the significant burdens caused by an additional trip requirement:

Some women might have to take a full or half day off of work or pay for child care to attend a counseling session, in addition to the time needed to attend the consultation with Planned Parenthood and the abortion procedure 72 hours later. That increased time, especially for women who live hours from the nearest Planned Parenthood clinic or pregnancy help center, contributes to the undue burden posed by the pregnancy help center requirement. Even a short delay that comes from compliance with the pregnancy help center requirement might push a woman past the gestational age limit at which she may receive an abortion.

*Planned Parenthood Minn., N.D., S.D. v. Noem*, No. 4:11-CV-04071-KES, 2021 WL 3711032, at \*11–12 (D.S.D. Aug. 20, 2021), *appeal filed*, No. 21-2922, 2021 WL 3711032 (8th Cir. Aug. 25, 2021) and No. 21-2913, 2021 WL 3711032 (8th Cir. Aug. 25, 2021).

All of these same burdens are present in this case. Under the Rule, patients would be required to either find the funding and make the logistical arrangements to stay in Sioux Falls for at least one more night or to make yet another (often lengthy) trip. These increased travel burdens

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<sup>9</sup> Although South Dakota's 72-hour requirement was initially preliminarily enjoined, *see Daugaard*, 799 F.Supp.2d at 1077, this claim was ultimately dropped from the litigation for unrelated reasons, and the waiting period is currently in effect.

will disproportionately affect low-income South Dakotans, who comprise a substantial portion of the clinic’s abortion patient population. In 2021, 31% of the patients who obtained a medication abortion, and 39% of all PPMNS’s patients, had incomes below 110% of the federal poverty line. Traxler Decl. ¶45. For many of these patients, “it stands to reason,” that they will be unable to afford the additional trip; this is “even more likely” for women who live farther away. *Daugaard*, 799 F.Supp.2d at 1063, 1065. Of patients seeking a medication abortion, close to 24% travel more than 150 miles per round trip to get to Sioux Falls health center for each visit. Approximately 11% travel more than 300 miles round trip. A third trip would bring their total mileage to over 450 miles and 900 miles respectively. Traxler Decl. ¶40.

The challenged Rule also “creates an incredible obstacle” for victims of domestic violence. *Daugaard*, 799 F.Supp.2d at 1066 (holding that for many women who are in such relationships, making additional trips to the clinic “is effectively impossible to do” because it increases “the chances of being ‘caught’ and punished by the abusive partner”). Some patients choose medication abortion specifically because they need to conceal their abortion from an abusive partner or family member; this is easier to do with medication abortion because it resembles a miscarriage. “A woman might decide to remain pregnant rather than risk her decision to have an abortion being shared with someone who is not supportive of that decision.” *Noem*, 2021 WL 3711032, at \*11; *see also Casey*, 505 U.S. at 893, 895 (law erected a substantial obstacle for “a significant number” of women “who do not wish to notify their husbands of their intentions” because “[m]any may fear devastating forms of [ ] abuse”).

The difficulty of arranging logistics related to additional and substantial travel, including “mak[ing] additional arrangements for childcare,” or taking additional “time off from work,” *Daugaard*, 799 F.Supp.2d at 1065, will also lead to delays in patients accessing care. Currently,

about 22% of patients who have a medication abortion do so about one week out from the clinic's medication abortion cut-off. Traxler Decl. ¶73. Delays in accessing abortion not only increase medical risks, *supra*, but can also render a patient ineligible for a medication abortion at all. *Daugaard*, 799 F.Supp.2d at 1065 (even delay of one week for “pregnant women who choose to undergo an abortion” can mean they are “denied the ability to undergo a medication abortion, which may be their chosen method of abortion, because of the delay”).

There is also the clear likelihood that some medication abortion patients who are able to make their first two trips find themselves—due to unforeseen circumstances, such as illness or weather or other life circumstances—unable to make the third trip. Because the health center is only able to provide abortion services two to three times per month, these patients may have to wait 1–2 weeks to meet with a physician. For some, this delay may mean that they are no longer within the gestational-age limit for medication abortion and would need a procedural abortion.

Finally, even in the scenario where Plaintiffs could somehow comply with the Rule would still result in overall decreased clinic capacity and fewer abortion appointments. PPMNS's physician pool is very limited and all of the physicians have numerous personal and professional commitments. Requiring these physicians to dedicate one more day per rotation—just to give patients the misoprostol—would mean they would have to devote their limited time in South Dakota to state-mandated tasks rather than the actual provision of abortion, which would in turn lead to patient delays across the board. In this way, the Rule would cause delayed care for all patients and all of the significant burdens associated with that delay, discussed *supra*. As numerous courts have recognized, such reduction of abortion services imposes serious burdens on the right to access abortion. *See supra* Argument Section I.A.2.b.<sup>10</sup>

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<sup>10</sup> The availability of out-of-state providers does not alter the analysis. *See, e.g., Schimel*, 806 F.3d at 918 (“[T]he proposition that ‘the harm to a constitutional right [can be] measured by

Plaintiffs have shown that they have a fair chance of prevailing—and indeed, are likely to succeed—on their claim that the Rule will place a substantial obstacle in the path of patients seeking abortions in South Dakota.

**B. The Rule Violates Plaintiffs’ and Their Patients’ Equal Protection Rights.**

Because the Rule’s differential treatment of patients and providers using misoprostol for abortion is not justified by any legitimate governmental interest, *see supra*, Plaintiffs are also likely to succeed on the merits of their claim that the Rule violates the Equal Protection Clause. The Rule’s imposition of unnecessary restrictions on physicians providing and patients seeking a medication abortion fails equal protection review under any level of scrutiny.

The Fourteenth Amendment guarantees that “[n]o State shall make or enforce any law which shall . . . deny to any person within its jurisdiction the equal protection of the laws.” U.S. Const. amend. XIV, § 1. The Equal Protection Clause is “‘essentially a direction that all persons similarly situated should be treated alike.’” *Stevenson v. Blytheville Sch. Dist. #5*, 800 F.3d 955, 970 (8th Cir. 2015) (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985)). Generally, the classification must bear a rational relation to a legitimate governmental purpose. *Schmidt v. Ramsey*, 860 F.3d 1038, 1047 (8th Cir. 2017). While rational basis review does not “require a perfect or exact fit between the means used and the ends sought,” *Walker v. Hartford Life & Accident Ins. Co.*, 831 F.3d 968, 978–79 (8th Cir. 2016) (quoting *United States v. Johnson*, 495 F.3d 951, 963 (8th Cir. 2007)), it is “not toothless,” *Kansas City Taxi Cab Drivers Ass’n, LLC v. City of Kansas City*, 742 F.3d 807, 810–11 (8th Cir. 2013).

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the extent to which it can be exercised in another jurisdiction . . . [is] a profoundly mistaken assumption.” (quoting *Ezell v. City of Chicago*, 651 F.3d 684, 697 (7th Cir. 2011)).

But where government action discriminates on the basis of a fundamental right, “we subject the law to strict scrutiny, and we will uphold it only if it is suitably tailored to serve a compelling state interest.” *Schmidt*, 860 F.3d at 1047 (cleaned up); *see also Mass. Bd. of Ret. v. Murgia*, 427 U.S. 307, 312 & n.3 (1976) (noting classifications burdening fundamental rights are reviewed under strict scrutiny); *Craigsmiles v. Giles*, 312 F.3d 220, 223 (6th Cir. 2002) (“When a statute regulates certain ‘fundamental rights’ (e.g. voting or abortion) . . . the statute is subject to ‘strict scrutiny.’” (quoting *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978))).<sup>11</sup>

The Rule cannot withstand even rational basis review, much less the heightened scrutiny which should be applied. The Rule singles out the use and dispensation of misoprostol in abortion settings for unique regulation, even though there is no meaningful difference in terms of safety between the use of misoprostol for abortion and its use in other settings where it may be dispensed by physicians and pharmacies like all other medications, including for the management of incomplete abortions, miscarriage management, and management of postpartum hemorrhage. The Rule therefore treats abortion providers and patients “differently . . . than similarly situated persons.” *Stevenson*, 800 F.3d at 972 (quoting *Koscielski v. City of Minneapolis*, 435 F.3d 898, 901 (8th Cir. 2016)).

In fact, misoprostol use for the management of incomplete abortions, miscarriage management, and postpartum hemorrhage actually involves a *higher* risk of bleeding than does its use for medication abortion. Grossman Decl. ¶31. Yet, South Dakota imposes no similar 24 to 72 hour mandatory delay and separate, in-person dispensing requirement when misoprostol is used in these other contexts. “[T]he differential treatment of abortion vis-à-vis medical procedures” that

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<sup>11</sup> As the Supreme Court noted in adjudicating the undue burden claim in *Whole Woman’s Health v. Hellerstedt*, it would be “wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue.” 136 S.Ct. at 2309–10.



carry at least the same level of risk as abortions “and probably more so” undermines any potential justification for the Rule. *Van Hollen*, 738 F.3d at 790–1 (holding that equal protection issue was “lurking” in the case). This differential treatment violates Plaintiffs’ and their patients’ equal protection rights. *See Romer v. Evans*, 517 U.S. 620, 631, 633 (1996) (law that on its face imposes a “special disability” on one group alone violates equal protection).

Indeed, as discussed *supra* Facts Part III, the Rule’s restrictions on the dispensing of misoprostol solely for medication abortion serves no legitimate state purpose, as they are a drastic departure from a well-established standard of care. The Rule provides no medical benefit to patients and instead threatens patients’ health. The Department’s only possible interest in promulgating the Rule is to prevent patients from exercising their right to choose abortion. Not only is such an interest outside the Department’s mandate, but it is also not legitimate. *Ranschburg v. Toan*, 709 F.2d 1207, 1211 (8th Cir. 1983) (“An intent to discriminate is not a legitimate state interest.”); *see also Whole Woman’s Health*, 231 F.Supp.3d 218, 229 (W.D. Tex. 2017) (fact that certain Texas regulations applied to abortion but not miscarriage or ectopic pregnancy was “evidence [the State’s] stated interest is a pretext for its true purpose, restricting abortions”).

The Rule’s additional burdens for patients and providers who use misoprostol in abortion settings creates an arbitrary classification in violation of the Equal Protection Clause.

### **C. Plaintiffs Will Be Irreparably Harmed Absent Court Intervention.**

The Rule would inflict serious, irreparable harm on South Dakotans seeking, providing, and assisting with abortion. As discussed *supra*, the Rule violates multiple constitutional rights of Plaintiffs and their patients. “Constitutional violations, however brief, are unquestionably irreparable.” *Daugaard*, 799 F.Supp.2d at 1076; *see also Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F.Supp.3d 1213, 1321 (E.D. Ark. 2019) (“[T]he deprivation of constitutional rights

‘unquestionably constitutes irreparable injury.’” (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)); *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action*, 558 F.2d 861, 867 (8th Cir. 1977) (“Planned Parenthood’s showing that the ordinance interfered with the exercise of its constitutional rights and the rights of its patients supports a finding of irreparable injury.”). There can be no doubt that the denial of medication abortion and/or the travel and financial burdens on patients of an extra trip, as well as the delay and potential outright denial of abortion that the Rule would cause, *see supra*, are irreparable. This prong therefore favors Plaintiffs.

## **II. The Balance of Equities Decidedly Favors Plaintiffs.**

Plaintiffs’ and their patients’ interest in preserving their constitutional rights while this case is pending outweigh any harm to Defendants that may flow from an injunction. *See Dataphase Sys., Inc.*, 640 F.2d at 113. Plaintiffs’ requested relief will simply preserve the longstanding status quo in South Dakota—allowing Plaintiffs to dispense misoprostol in accordance with a well-established standard of care—preventing disruption of abortion services in the state, as well as preventing the harms to patient health that would flow from the Rule. *See Ferry-Morse Seed Co. v. Food Corn, Inc.*, 729 F.2d 589, 593 (8th Cir. 1984) (“The primary function of preliminary injunction is to preserve the status quo[.]”); *see also Little Rock Fam. Plan. Servs. v. Rutledge*, 398 F.Supp.3d 330, 424 (E.D. Ark. 2019) (holding balance of equities favors preliminary injunctive relief in challenge to two abortion bans); *MKB Mgmt. Corp. v. Burdick*, 954 F.Supp.2d 900, 913 (D.N.D. 2013) (holding balance of equities favors preliminary injunctive relief in challenge to six-week abortion ban). Further, there can be no harm to South Dakota or the Department from prohibiting the enforcement of a patently unconstitutional rule. *See Little Rock Fam. Plan. Servs.*, 397 F.Supp.3d at 1322 (enjoining abortion bans and restrictions would not irreparably harm the State because “the State has no interest in enforcing laws that are unconstitutional”). This is

especially true here where, as explained above, the Rule does not even further the Department's asserted interests.

### **III. Temporary Injunctive Relief Would Serve the Public Interest.**

Enjoining enforcement of the Rule and preserving South Dakotans' ability to access safe, early abortion in South Dakota as is their constitutional right would serve the public interest. As the Eighth Circuit has made clear, "the protection of constitutional rights is always in the public interest." *Rounds*, 530 F.3d at 752. That is because it is axiomatic that the public interest is served by upholding the Constitution and preventing the enforcement of unconstitutional laws. *See, e.g., Daugaard*, 799 F.Supp.2d at 1077 (finding public interest furthered by protecting constitutional right to abortion); *Little Rock Fam. Plan. Servs.*, 397 F.Supp.3d at 1322–23 (same). Because the Rule is clearly unconstitutional, *see supra*, a TRO and/or injunctive relief preventing its enforcement would serve the public interest.<sup>12</sup>

### **CONCLUSION**

For the foregoing reasons, this court should grant Plaintiffs' Motion for a Temporary Restraining Order and a Preliminary Injunction.

Dated: January 19, 2022

/s/ Stephanie Amiotte

Stephanie Amiotte (SD Bar #3116)  
Andrew Malone (SD Bar #5186)  
American Civil Liberties Union of North  
Dakota, South Dakota, and Wyoming  
PO Box 91952  
Sioux Falls, SD 57109  
Telephone: (605) 332-2508

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<sup>12</sup> Because there is no prospect of monetary damages and Defendants would not be harmed by relief that merely maintains the status quo, and because Plaintiffs are serving a public interest in acting to protect constitutional rights, this Court should waive the F.R.C.P. 65(c) security requirement. *See Richland/Wilkin Joint Powers Auth.*, 826 F.3d at 1043 (affirming district court's waiver of bond requirement "based on its evaluation of public interest").

samiotte@aclu.org  
amalone@aclu.org

Diana O. Salgado\*  
Planned Parenthood Federation of America  
1110 Vermont Avenue, NW, Suite 300  
Washington, District of Columbia 20005  
Telephone: (212) 261-4399  
diana.salgado@ppfa.org

Michael Drysdale\*  
Dorsey & Whitney LLP  
50 South Sixth St., Suite 1500  
Minneapolis, MN 55402  
Telephone: (612) 340-5652  
drysdale.michael@dorsey.com

\*Application for admission *pro hac vice*  
forthcoming

ATTORNEYS FOR PLAINTIFFS

### **CERTIFICATE OF COMPLIANCE**

This brief complies with South Dakota Local Civil Rule 7.1(B)(1) because—according to Microsoft Word 2018, the word processing program used to draft this brief—it contains 8,164 words, not including the cover page, table of contents, signature block, certificate of service and this certificate. *See* D.S.D. Civ. LR 7.1(B)(1); Fed. R. Civ. P. 32(f).

This 19th day of January, 2022.

/s/ Stephanie Amiotte  
Stephanie Amiotte  
American Civil Liberties Union of  
North Dakota, South Dakota, and  
Wyoming PO Box 91952  
Sioux Falls, SD 57109  
Telephone: (605) 332-2508  
samiotte@aclu.org

### **CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing Brief in Support of Motion for Temporary Restraining Order and Preliminary Injunction was sent on the 19th day of January, 2022, via facsimile or electronic mail to the following:

Kristi Noem, Governor  
South Dakota Office of the  
Governor  
500 E. Capitol Ave.  
Pierre, SD 57501-2536  
Phone: (605) 773-3212  
Fax: (605) 773-4711

Joan Adam, Interim Secretary  
of Health  
South Dakota Department of  
Health  
600 E. Capitol Ave.  
Pierre, SD 57501-2536  
Phone: 605-773-3361  
Fax: 605-773-5683

Philip Meyer, D.O., President  
South Dakota Board of  
Medical and Osteopathic  
Examiners  
101 N. Main Ave., Suite 301  
Sioux Falls, SD 57104  
Phone: (605) 367-7781  
Email: sdbmoe@state.sd.us

This 19th day of January, 2022.

/s/ Stephanie Amiotte  
Stephanie Amiotte